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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,657	12/28/2001	Sukanta Banerjee	42970-7CII	6168

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EXAMINER

DO, PENSEE T

ART UNIT	PAPER NUMBER
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1641

MAIL DATE	DELIVERY MODE
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05/26/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/032,657	BANERJEE ET AL.	
	Examiner	Art Unit	
	Pensee T. Do	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment Entry & Claims Status

The amendment filed on February 27, 2009 has been acknowledged and entered.

Claims 18-22 are pending and being examined.

Priority

This application, 10032657, filed 12/28/2001 is a continuation in part of PCT/US01/20179, filed 06/21/2001 PCT/US01/20179 which claims priority from Provisional Application 60213106, filed 06/21/2000.

Claimed Invention

18. (previously presented) A method of multiplex analysis of analytes in a solution, comprising:

providing a plurality of magnetically polarizable microparticles of two or more types wherein different types bear an optically distinguishable signature, and the different types display different capture moieties on their surfaces capable of binding to different analytes;

suspending the microparticles in a first solution containing, or suspected to contain analytes of interest, under conditions permitting the capture of analytes by the capture moieties, and wherein an optical signal is generated following such capture; using a magnetic field to assemble the microparticles in a planar array on a designated

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section of a substrate wherein the spacing between particles within the array can be varied by varying the strength of the magnetic field; and

imaging the optically distinguishable signatures associated with the microparticles and the optical signals, and correlating the optical signals with microparticles having particular optically distinguishable signatures to determine which analytes are bound by which capture moieties.

Maintained Rejection(s)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al. (US 7,115,884 filed on October 6, 1997) in view of Wang (US 6,013,531) and further in view of Farber (US 5,602,042).

Walt teaches a method of multiplex analysis of analytes in a solution, comprising providing a population of microspheres having a plurality of different subpopulations, each subpopulation comprises microspheres having distinct optical response signature (see col. 5, lines 5-30) or each microsphere is encoded with a fluorescent dye (see col. 11, lines 6-10) and has capture moieties coated thereon for binding to the target analyte

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(see tables II and III); the microspheres are assembled into an array and a sample is added to such array; illuminating the array; decoding the array by comparing the response of the entire sensor array to a known analyte or to a library of optical response signatures for its corresponding bead subpopulation type, where the optical response signature to various analytes has been previously measured and recorded. (see col. 5, lines 5-29). The beads and array images are recorded with a CCD frame transfer camera (see col. 17, lines 38-40).

However, Walt fails to teach using magnetic beads and applying a magnetic field at various strength to form an assembly of beads; Walt also fails to teach replacing the first solution with a second solution.

Wang teaches fluorescent magnetic beads for use as markers in assay comprising a polymeric core coated evenly with a layer of polymer containing magnetically responsive metal oxide and a fluorescent dye or a combination of fluorescent dyes. (see col. 1, line 40-col. 2, line 9). Wang teaches using the magnetic particles in an assay by incubating the magnetic particles with a sample, magnetically separate them from the sample (first solution) and wash three times and resuspend in 30 ul of IBS (see example 35).

It would have been obvious to one of ordinary skills in the art to use fluorescent magnetic beads as those taught by Wang as particles in the method of Walt because the magnetic fluorescent particle in Walt can be used as a separation means and as a label at the same time and thus avoid the use of a second label molecule. Regarding claim 21, it is well known to one of ordinary skills in the art that after magnetic

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separation, a wash step must be performed to ensure all the non-bound molecules from the sample which might interfere with the detection are removed and a step of resuspending the magnetic particles bound with analytes in a buffer (second solution) is also a must in order to carry out the detection step as taught by Wang. It would have been obvious to one of ordinary skills in the art to replace the first solution (sample) with a second solution such as a buffer (IBS) as taught by Wang in the method of Walt to disperse the particles in such solution as a preparation for the detection step.

However, Walt and Wang fail to teach applying a various strength magnetic field to the magnetic beads to form an assembly of beads.

Farber teaches collecting particles such as cells tagged with magnetic beads against a solid surface using a magnet element which generates magnetic field at various strength to control the spatial distribution of the cells collected against the surface. (see col. 3, lines 59-65).

It would have been obvious to one of ordinary skills in the art to immobilize magnetic particles to a substrate using a magnetic field according to the method taught by Farber to assemble the magnetic particles into an array for use in the combined method of Walt and Wang so that analysis can be performed directly on a surface for large scale identification or separation.

Response to Arguments

Applicant's arguments filed February 27, 2009 have been fully considered but they are not persuasive.

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Applicants argue that Farber fails to teach "wherein the spacing between the particles within the array can be varied by varying the strength of the magnetic field". Applicants submit that "Farber discusses a magnetic separation system that is capable of collecting magnetic particulates dispersed in a solution onto a collection surface, using fixed or rotating magnetic elements which allow the applied magnetic field to be connected at selected locations on the collection surface. When the collector surface is contacted with a fluid containing magnetic particles, the collector surface accumulates magnetic particles in the areas of high magnetic field, where the particles are held immobilized. This system is able to control spatial distribution of the collected particle/particle aggregates by positioning the magnetic elements (described in col. 3, lines 59-65). Once the magnetic elements are in place, the spatial magnetic field distribution and hence the final collection pattern of the particles (or the spacing between the particles) is fixed and cannot be changed by changing the strength of the magnetic field. Thus, the system is not capable of achieving "wherein the spacing between the magnetic particles within the array can be varied by varying the strength of the magnetic field".

Farber, in col. 3, lines 59-65 describes:

"A further feature of the invention is that the magnet and the plate are preferably configured to direct the flow of tagged particles to selected portions of the plate surface. For example, the magnet element can be arranged with the plate element so that the generated magnetic field is stronger at selected areas of the plate surface. ***The provision of a spatially varying magnetic field enables the device to control the ~~spatial~~ distribution of the cells collected against the plate.*** In a preferred embodiment, the magnet element is positioned vertically above the plate, and couples to the plate at select locations for providing a stronger magnetic attraction at these locations. Alternatively, the magnet element can be fixed at one point on the

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periphery of a rotating disc that is disposed vertically above the plate. ***The rotating disk moves the magnet element relative to the plate to spatially vary the magnetic field. This configuration achieves a more uniform spatial distribution of the particles collected against the surface.*** Other configurations for spatially varying the magnetic field can use a distributed array of magnet elements that can be selectively activated and deactivated.”

The claimed invention requires that “wherein the spacing between particles within the array can be varied by varying the strength of the magnetic field”. This is interpreted as by varying the magnetic field strength, the spacing between the particles is varied.

Farber, as discussed above, teaches that “the magnetic field is varied and spatially varying the magnetic field enables the device to control the spatial distribution of the cells/particles collected against the plate”. Thus, Farber meets the requirement of the claimed invention by teaching applying a varied magnetic field to control the spatial distribution of the cells/particles collected against the plate.

Applicants further submit that there is no evidence that the Farber magnetic collection system can “assemble the microparticles in a planar array”.

Farber teaches the collection surface is a plate which is planar. Furthermore, the step of assembling the magnetic particles into an array is taught in Walt as discussed in the rejection above. Farber is not relied upon for the teaching of assembling the magnetic particles in a planar array.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Pensee T. Do/
Examiner, Art Unit 1641

/Mark L. Shibuya/
Supervisory Patent Examiner, Art Unit 1641